APPENDIX II
CLEAN COPY OF REPLACEMENT SPECIFICATION

HYDRAULIC DEVICE FOR INJECTION OF BONE CEMENT IN PERCUTANEOUS VERTEBROPLASTY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is the National Phase Application of International Application No. PCT/MX2003/000027 filed March 14, 2003.

TECHNICAL FIELD

[0002] This invention relates generally to medical procedures where it is required to inject a dense or viscous fluid through a needle, in a particular way the viscous material is polymethylmethacrylate. It is used in procedures like percutaneous vertebroplasty, kyphoplasty or other surgical events of the field. It has applications in other areas where it is required to apply at distance a dense and viscous liquid.

BACKGROUND OF THE INVENTION

[0003] Percutaneous vertebroplasty is a minimally invasive interventional radiological procedure that consists of injecting bone cement (Polymethylrnethacrylate, PMMA) in the vertebral body by trans-pedicular or oblique approach through a bone biopsy needle.

[0004] It was developed in France in 1984 for the treatment of aggressive or painful degenerative conditions of vertebral bodies. For its analgesic effect, its use was quickly extended for the treatment of metastatic lesions or myeloma and mainly in fractures or vertebral collapse due to osteoporosis. The procedure is indicated in those cases that are presented with severe and disabling pain that doesn't respond to conservative measures such as: corset use, analgesic and anti-inflammatory treatment or bed rest.

[0005] Most of the patients with this suffering are between the 6th and 8th decade of life. In this group of advanced age, the immobilization resulting from vertebral fractures has severe

consequences in their general medical conditions, it predisposes them to cardiopulmonary, intestinal, circulatory complications, etc. Besides pain, the psychological effects can be devastating, it deteriorates the quality and reduces the expectation of life.

[0006] Vertebroplasty is a procedure that is carried out in hospital facilities that requires specialized medical personnel. It is performed in a cath lab, and it requires of the use of radiological equipment with high resolution fluoroscopy, mounted in a C arm. Currently, this injection is carried out in a manual and direct way and the operator is exposed to ionizing radiation every time that he/she practices a vertebroplasty. The injection of bone cement is made with fluoroscopic control, connecting an insulin syringe to the needle. This implies that the surgeon is in direct contact with the patient and therefore, overexposed to primary or secondary ionizing radiation during the lapse of the procedure of the vertebroplasty.

[0007] The primary radiation is the X ray beam coming from the X ray tube and received by the patient in a direct way. The secondary radiation it the one resulting on the deviation of the primary beam in the patient's body tissues and doesn't contribute to the formation of a diagnostic image, it is spread in all directions and it is the main source of exposure of medical personnel.

[0008] An insulin syringe is typically used since a small diameter barrel is required to have less resistance for the manual injection of high viscosity bone cement. Each syringe is filled approximately in half or two thirds of its capacity to avoid bending or breaking the plunger when exercising the required injecting pressure that may be considerable. The volume needed to obtain the expected results varies from 3 ml up to 9 ml, therefore, 5 to 18 syringe exchanges are necessary, this favors the solidification of the polymethylmethacrylate and it can prevent to inject the wanted quantity.

[0009] If larger diameter syringes are used, manual pressure is insufficient due to the density and viscosity of the bone cement and becomes necessary to employ a mechanical device to be able to exercise the required pressure. At present, there are commercially available devices such as pressure gun type or threaded plunger mechanisms connected directly to the needle that deposit the cement in the bone or through a high pressure short tube. The use of a long tube would have considerable resistance to the flow of the cement, favoring its solidification.

[0010] In most of these devices the syringe is not interchangeable, it is loaded with the total volume to inject and therefore, has a larger diameter, and increased resistance to the flow of the cement becomes worse with time due to solidification of cement.

[0011] On the other hand, conventional hypodermic syringes are not designed for high pressure injection, the plunger and the fingers supporting wings bend easily.

[0012] The devices of the previous technique solve only the mechanical problem of injecting the dense and viscous cement through the needle, but they are focused on exercising the necessary pressure directly on the patient or at a very short distance of the radiation source. They don't allow the operator to maintain an appropriate distance to reduced exposure to secondary radiation at acceptable levels according with the international radiological protection norms.

[0013] On the other hand, some mechanical devices do not allow control or manual sensibility of the exercised pressure and speed of the injection of the cement, important factors in the prevention of undesirable leaks and complications. Some devices that apply cement in the current state of the art are for example:

[0014] United States Patent Publication No. 2003/0018339, to Higueras et al, published January 23th of 2003, discloses a device for the controlled injection of bone cement, mounted in a syringe loaded with the cement as a cartridge, which is discharged by a threaded metallic plunger placed in the other end of the device. The device is useful for controlling the pressure exercised on the plunger of the syringe, but it is a short device in which the operator is near the patient. It also contains the total load of cement.

[0015] On the other hand, due to the quantity and viscosity of the cement, it has a dynamic memory that doesn't allow sudden interruption of the injection.

[0016] United States Patent Publication No. 2002/0156483, to Voellmicke et al, published October 24th of 2002, discloses a vertebroplasty device having two compartments, one for mixture of the cement and the other for storage and injection into the bone. This dual chamber device for blending and injection consists of a delivery chamber with a plunger moving axially. The chambers are in communication through a check valve that only allows the passage

of the cement in one direction. An extra force can be exercised on the plunger by means of a lever that increases the mechanical force and therefore the pressure in the injection chamber. This is a device in which it is necessary to work the piston of the blending chamber and the piston of the injection chamber to empty one and fill the other one alternatively. It is a short device, with the result that it is necessary to be near the patient and doesn't reduce the exposure to secondary ionizing radiation.

[0017] United States Patent Publication No. 2002/0099384, to Scribner et al, published July 25th of 2002, discloses a system and method to treat vertebral bodies. It is a special syringe with two concentric plungers. The first chamber has a first transverse section and a second chamber is smaller than the first one. Both chambers communicate with each other. The first chamber includes a gate to receive the material inside the filling instrument, the second chamber includes a gate to discharge the contained material. A first plunger suited to pass through the first chamber and displace the material. A second plunger to pass through the interior of the first plunger's concentric hole and reach the interior of the second chamber to displace the material through the exit in the second camera to inject into the needle toward the interior of the vertebral body. Although this device provides control in the injection of the bone cement, the operator is too near the patient.

[0018] In general, the injection devices have a bolster that impels the viscous fluid by means of a manual trigger moved by a screw mechanism (inclined plane), there are others that have a gun like body such as the device of the Patent Application of the United States Patent Publication No. 2002/0049448, to Sand et al, published April 25th, 2002. It has a tubular body that stores a viscous flowing material (bone cement). The body is a longitudinal body with a providing end and a driving end, a plunger housed inside the tubular body that displaces the flowing material along the longitudinal axis of the tubular body, and a driving mechanism that has a handle like a gun to hold with a hand, while injecting with the other hand by means of the plunger that advances due the pressure exerted by a threaded mechanism. These mechanisms with big deposits have the inconvenience that the cement can end up solidifying in the conduit at the time of application and impede to apply the total amount of cement inside the affected vertebral body. On the other hand, with the excess of pressure generated by these devices, the

cement could leak outside of the vertebral body, since the fluid (PMMA), for its viscosity, possesses a remaining flowing memory that may be difficult to control.

[0019] United States Patent No. 6,348,055, to Preissman, published February 19th of 2002, provides a bone cement applying device with screw mechanism in which the preparation of the total volume of cement is made. This mechanism has an intermediate stabilizer that avoids the need to turn the whole device during the application of pressure to the fluid. The stabilizer is a lever perpendicular to the screw body that can be sustained with one hand, while with the other hand exercises the pressure to inject the cement inside the vertebral body. This device is also operated very near the patient and therefore, the operator is exposed to secondary ionizing radiation. Another inconvenience is that if the cement "solidifies in the system and has not reached the vertebral body in the proper amount, it is necessary to make another preparation of another needle in a different and appropriate position for the new requirement.

[0020] United States Patent Publication No. 2002/0010431, to Dixon et al, published January 24th, 2002, discloses a screw device for high pressure injection with a threaded axis that impels a plunger inside a chamber filled with viscous bone cement. This device has the inconveniences that one doesn't have manual sensitivity and control of the pressure exercised and it is not easy to exchange the syringes with the bone cement. As a matter of fact, it is the only syringe of the cartridge.

BRIEF SUMMARY OF THE INVENTION

[0021] Among the several objects of the present invention, a better control of the pressure in the placement of bone cement or other viscous materials in the bone is provided. The invention facilitates the injection of viscous filler in trabecular bone or a cavity formed in the vertebral body.

[0022] Another object of the present invention it is to provide a hydraulic device to treat vertebral fractures and reduce the pain, stabilize the vertebral body, obtain higher resistance to compression, and avoid further collapse and at the same time to allow early mobilization of the patients and improve their quality of life.

[0023] It is still another object of the present invention to provide a device for the injection of viscous material in the vertebral body that allows the operator to keep and appropriate distance (1.0 m to 1.5 m) in order to reduce exposure to ionizing radiation at acceptable levels within the international norms.

[0024] It is also another object of the present invention, to provide a hydraulic press like device using syringes of unequal caliber (3 and 10 ml) to exercise hydraulic pressure at distance transmitted from a proximal, manual syringe of smaller caliber, through the polyethylene tube until the distal or injecting syringe.

[0025] It is another object of the present invention to provide a pressure cylinder with mechanical advantage complementary to a hydraulic system of syringes for injection at distance of a polymethylmethacrylate cement in the cancellous bone of a vertebral body. This way, the overexposure of the operator to ionizing radiation is reduced.

[0026] It is still another object of the present invention to provide a hollow cylinder or pressure body in the shape of an inverted syringe to form a hydraulic device that allows manual control on the volume and velocity of injection polymethylmethacrylate (PMMA) and also immediate interruption of the pressure applied on the fluid.

[0027] It is still another object of the present invention, to provide a device that prevents the movements or abnormal displacements of the needle during the injection and syringes exchange (1 or 2 exchanges may be necessary), to reduce time loss and allow to maintain the bone cement loaded syringes in a recipient or cold atmosphere to slow time of solidification.

[0028] It is another object of the present invention to provide a device that uses syringes from 3 to 5 ml that require smaller injection pressure, and can be exchanged easily with a single 90° rotation movement of a hub lock.

[0029] It is still another object of the present invention to provide a device for injection of viscous material that can be manufactured of plastic, aluminum or any other disposable light-weighted material for single use or suitable for re-sterilization, sturdy enough to support the pressure of injection.

[0030] It is another object of the present invention to provide a flexible hydraulic, light-weight device that prevents the movements or unwanted displacements of the needle during the injection.

BRIEF DESCRIPTION OF THE DRAWINGS

[0031] Figure 1 represents the connection outline of a hydraulic press injection device of the present invention;

[0032] Figure 2 represents an injection device with a screw type threaded plunger of the previous technique;

[0033] Figure 3 represents an injection device of the previous technique, which has a chamber to make the mixture, another to exercise the injecting pressure wherein each chamber contains a check valve in their exit holes to avoid re-flow;

[0034] Figure 4 represents an injection device of the previous technique, which contains a larger capacity syringe in which the total amount of bone cement mixture is placed to inject and impelled by a threaded plunger;

[0035] Figure 5 represents a device of the present invention corresponding to the transverse view of the piston together with the rubber cap;

[0036] Figure 6 represents a smaller, manual syringe of the invention for control of the device with the plunger and rubber cap;

[0037] Figure 7 represents an actuator syringe, the conduit (7) that transmits the pressure to the larger diameter device (B) and the way to place the plunger (A) of the injecting syringe that contains the material and the injection needle;

[0038] Figure 8 represents a hydraulic press according to the theoretical basic principles of the present invention; and

[0039] Figure 9 represents the pressure transmitted in the tube and the exit force generated, which pushes the plunger that injects the material through the needle.

DETAILED DESCRIPTION OF THE INVENTION

[0040] The present describes a new device and method to treat affections of the bones, specifically, in the treatment of osteoporotic or fractured vertebral bodies.

[0041] These bone structures have different pathological states of diverse ethiology (trauma, osteoporosis, primary bone tumors or metastasys, etc.). An alternative of treatment to stabilize and to consolidate this structures consists on the injection of a bio-materials such as polymethylmethacrylate in the interior of the vertebral body for healing purpose.

[0042] The injection of biomaterials such as bone cement is carried out by means of a hydraulic device exerting pressure on small caliber conventional syringes connected directly to the needle, since the cement has the property of becoming hard quickly.

[0043] The theoretical basic principle for the operation of the device of the present invention consists on the amplification of the hydraulic pressure generated at distance and transmitted by the hydraulic tube.

[0044] In reference to Figure 8, the most frequent application of the Law of Pascal is the hydraulic press that consists of two asymmetric columns of liquid. This principle is applied in mechanical devices of engineering areas where the columns are different in the size or diameter of the transverse section. In accordance with the Law of Pascal, a pressure applied in one of the columns is transmitted entirely and in all directions. Therefore, if a force F_1 is applied on the area piston A_l, it will cause an exit force F_0 that acts on an area A_0 of the piston. This way, the entrance pressure is the same to the exit pressure, that is to say:

$$F_1/A_1 = F_0/A_0$$

[0045] The ideal mechanical advantage of the device is similar to the relationship of the exit force with regard to the entrance force:

$$VM = F_0/F_1 = A_0/A_1$$

[0046] Where a small entrance force can be multiplied (A_0/A_1 times) to produce a larger exit force (F_0), using an exit piston with a larger area than that of the entrance piston. The exit force will be given by:

$$F_0 = F_1 A_0/A_1$$

[0047] If friction is disregarded, in an ideal situation the entrance work should be the same as the exit work. Therefore, if the force F_1 travels a distance S_1 while the exit force F_0 travels a distance S_0, there is equality:

$$F_1S_1 = F_0S_0$$

[0048] The mechanical advantage can be expressed in terms of the distances traveled by the pistons:

$$VM = F_0/F_1 = S_1/S_0$$

[0049] It is observed that the mechanical advantage is obtained at expenses of the distance that the entrance piston travels.

[0050] In reference to Figure 9 that describes the body (B) and area (95) of the piston of larger area of the present invention, the pressure P_I that is transmitted through the incompressible fluid, either water or oil, present in the flexible tube (not shown) that generates an exit force F_0. The attachment (2) for the lateral wings of the injecting syringe that contains the bone cement acts as coupler to the device, the wings enter tightly in the internal peripheral groove (70) diametrically opposed inside the bolster(header) of the body of the device object of the present invention, with a turn of 90° either clockwise or counterclockwise. The plunger of the syringe enters in the longitudinal central space (95) of the body (B).

[0051] Returning to Figure 1, the hydraulic device consists of four main parts arranged one after another in such a way that allows to inject at a distance and in a controlled way (regarding the pressure) viscous materials such as polymehylmethacrylate used in percutaneous vertebroplasty for the reestablishment (without surgery) of a vertebra with osteoporotic fractures.

[0052] The device here described is designed to inject at distance a polymethylmethacrylate suspension with viscous consistency, directly in the cancellous bone of the vertebral bodies by means of a syringe loaded with the bone cement attached to a bone biopsy needle. The device consists of four main parts, "injecting syringe" in vicinity to the patient, "pressure exerting body," "hydraulic transmission tube" and "manual syringe". In this, the fingers of the operator exercise the controlled force. This control is carried out by the operator's tactile sensitivity. This device provides a hydraulic system for polymethylmethacrylate injection at a variable distance from the patient (usually 1 m to 1.5 m).

[0053] The injecting syringe is a commercially available, disposable 3 ml[[.]] hypodermic syringe that (a) is placed next to the patient, loaded with the bone cement ~~that~~ and consists of a plunger (11) that pushes the material (CO) to be injected in the vertebral body through a bone needle (CA), (not shown). This syringe couples tightly in a revolved way, by means of the opposed wings of support (b), in a peripheral groove in the internal face of the bolster (2) of the pressure body, it is coupled by means of the opposed wings (b) used as support for the fingers for injection in the usual way. These wings (b) are placed in the entrance guide and rotated, either clockwise or counterclockwise an angle of 90°, to stay in tightly fixed to avoid inadvertent detachment and loss of the pressure. The injection needle is coupled by rotating the threaded distal end (CA) in the usual way of common plastic syringes in order to avoid spillage of the material to be injected due to the high pressure exercised on the plunger (c) and its end (3). For exchange, the empty syringe is detached from the needle, and then from the pressure device by means of a 90° rotation, discarded (2) and replaced with another loaded syringe prepared in advance and stored in a cold environment to delay curing and hardening of the cement. The syringe (a) is of 3 or 5 ml capacity.

[0054] The pressure exerting body consists of distal inverted syringe body (1) of larger diameter that the syringe at the proximal end of the complete device. It has a bolster (2) open to atmospheric pressure that contains an internal peripheral groove where the opposed supporting wings of the injecting disposable hypodermic syringe are coupled (b) with a turn of 90°. Its interior is open to the atmospheric pressure and receives the plunger of the injecting syringe (c) in a extended position to make contact with the rigid surface of the piston (3) The piston moves

tightly with respect of the internal wall of the device (1) by means of a rubber cap (4), to maintain a closed hydraulic space (5). The distal pressure is transmitted to the piston through the opening or mouthpiece (6) connected to the flexible tube of polyethylene or similar material (7) by means of the hydraulic fluid (10). The rigid surface of the piston (3) exercises pressure (which has been increased by the device) on the plunger(11) of the injecting syringe. The body (1) is manufactured of transparent plastic, aluminum or any other suitable light-weighted and rigid material. Other characteristics of the body will be described (1) with more detail in Figures 5, 7 and 9.

[0055] The hydraulic tube for pressure transmission (Pascal's Principle), is a tube or flexible hose of polyethylene or similar light weight material, with appropriate diameter to couple in the distant and proximal ends of the syringes. The length can vary, most commonly from 1.0 m to 1.50 m. The tube is also resistant to the internal pressure. The tube is loaded of water, oil or other incompressible fluid (10) to integrate together with the manual syringe and the body of the closed hydraulic system.

[0056] The manual syringe (8) has a smaller diameter than the pressure body (1) in a 2/1, 3/1 or 4/1 ratio that may vary according to the necessity of each case. According to the hydraulic press described in Figure 8, the length of the manual syringe should be larger than that of the pressure body (1) with the purpose of containing enough volume to displace the piston the distance required to impel the plunger of the injecting syringe. This way, the quantity required of bone cement is deposited in the vertebral body.

[0057] The device works in the following way: a manual force is exercised on the plunger (9) of the manual syringe (8) in its extended position. The force exercises a pressure that is transmitted through the incompressible fluid (10) present in the flexible tube and in the chamber (5) of the pressure body (1). This pressure exercises an increased force on the plunger of the injecting syringe, due to the mechanical advantage of the relationship of areas or displacements formerly described. The plunger of the injecting syringe, in turn, exerts a force that impels (to) the material or cement to be injected in the patient's vertebral body through the bone biopsy needle. Once the total amount or content of the injecting syringe has been delivered, the plunger of the manual syringe is retracted to generate space inside the pressure body (1) by

retracting the piston to replace the emptied syringe with a loaded new syringe to continue the injection. Up to 10 ml of bone cement is required to achieve an suitable filling of the fractured vertebral body, therefore, 3 to 4 syringe exchanges may be necessary.

[0058] The bone needle stays in place during the procedure. That is to say, the movements or abnormal displacements of the needle during the injection are avoided. This provides several advantages: for the patient, since additional punctures are less frequent and for the operator with less problems of solidification of the cement.

[0059] Another advantage of the device is that the transmission of the pressure is immediate, that is to say, doesn't have a dynamic memory by effects of the increasing viscosity due to the solidification in the injection conduit specially with prolonged injections, prone to happen in the injecting devices of the previous technique that are loaded with the complete volume of cement to be placed. On the other hand, the threaded plunger doesn't allow tact sensibility regarding the exercised pressure and therefore favors unwanted leakage of the bone cement due to the dynamic memory of the material.

[0060] To this respect we have devices of the previous technique such as the (20) figure 2 that consists of a threaded plunger (23) that impels the contained cement in the camera (24) and a refilling deposit (22) that in turn feeds the camera by means of a plunger (21); A handle (25) that serves for support to the other hand of the operator to facilitate exercise the intense force so that the cement flows in a short tube (26) and it is injected through the needle (27).

[0061] The device (30) of the previous technique of the figure 3 contains two cameras (35) (32) connected by a valve check in the conduit (37). The bone cement is mixed In the camera (35) and impelled to the injection camera (32) by means of a plunger(36), once in the injection camera the cement is impelled by the piston (38) of a plunger (34) moved by a lever that provides the required force (33), forcing the cement through the opening (31) that in turn contains a valve check that closes in the recharge operation.

[0062] The figure 4 illustrate another device (40) of the previous technique for injection of polyrnethylmethacrylate. In this one the threaded plunger (41) has a crank (42) in the end to

facilitate impel the total content of the syringe (45), and supporting elements (43) (44) for the other hand of the operator in the action of injection of the bone cement.

[0063] The figure 5, represents a cut profile and front view the body of pressure (50) that shows the groove of the bolster (2) where the injecting syringe that contains the bone cement is secured. Also presents the front view and profile of the piston (51) and the rubber cap (52) that avoids spillage of the hydraulic fluid in the action of transmission of the pressure. With this body of pressure, object of the present invention, is possible to transmit the pressure at distance and therefore reduces exposure of the operator to secondary ionizing radiation coming from the patient at the time of placement of the bone cement. This body of pressure complies with the characteristic of being light-weighted, may be disposable or reusable, manufactured of plastic, aluminum or other suitable material able to support sterilization.

[0064] The figure 6, represents frontal and lateral views of the manual or impulsion syringe (60), and plunger (61) where the rubber cap is placed (62) to avoid leakage of the hydraulic fluid. The bone cement should be kept in a cold environment before it is applied so it is maintain fluid to avoid solidification in the needle.

[0065] In the figure 7, the transverse cut of the cylindrical hollow body of pressure is described (B) that houses the plunger (A) of the injecting syringe secured in the peripheral groove (70) of this body of pressure, it is connected to the flexible tube (7) that transmits the hydraulic pressure (10), exercised from the manual or impulsion syringe (C) by means of its plunger (9). Here is illustrated the way the injecting syringe is attached to the body of pressure, Once introduced the plunger (A) in the opening of the body of pressure (B) the syringe is turned 90° in such a way that the body of the syringe is tightly secured to proceed with the injection of the bone cement.

[0066] The use of small diameter syringes in the application of the cement has the advantage of less resistance to flow, so a more viscous cement can be injected to reduce the possibilities of leakage from the vertebral body.

[0067] The experts in the technique expect other embodiments of the invention might exist, that is to say, embodiments of instruments built according to the teachings of the present

invention. Because many of the characteristics of the embodiments are similar to those previously described. Peculiar embodiments of the invention have been illustrated and described in those that it will be obvious for those experts in the technique that several modifications or changes can be made without leaving the reach of the present invention. The above-mentioned tries to cover with the added claims so that the changes and modifications fall inside the reach of the present invention.